

# Exhibit B

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

**IN RE: ETHICON, INC. PELVIC  
REPAIR SYSTEM PRODUCTS LIABILITY  
LITIGATION**

**Master File No. 2:12-MD-02327  
MDL No. 2327**

---

**THIS DOCUMENT RELATES TO:**

**JOSEPH R. GOODWIN  
U.S. DISTRICT JUDGE**

*Cheryl Berden, et. al. v. Ethicon, Inc.*  
**Case No. 2:14-cv-21966**

**SUPPLEMENTAL REPORT OF DR. VLADIMIR IAKOVLEV FOR ISSUES RELATED  
TO MERSILENE MESH**

**I. General Issues of Mesh Erosion/Exposure through Skin or Mucosa**

Mesh exposures can be separated into two groups: primary and secondary. Primary exposure occurs at a never healed operative wound, while secondary erosion occurs either through a healed scar or through initially unaffected tissues. The secondary type of erosion can occur sometimes months and years after mesh implantation.

For the primary type, exposure through a never healed operative wound is either caused or complicated by the presence of a foreign object in the wound. Although it can be partially dependent on surgical technique, the mesh itself is a major factor in the early mesh exposures. Presence of a foreign body in a wound is a known cause for retarded healing. [1] The foreign object acts as a physical barrier in the wound. Also, multiple other factors such as interrupted blood

supply that cannot be restored quickly through the mesh, foreign body type inflammation, bacterial retention by the foreign body and superimposed acute inflammation slow healing.

In relation to the secondary type of erosions, or extrusion through healed or unaffected skin or mucosa, published literature indicated that mesh specific factors play a role. [2] [3] Solid silicon strips or silicon coated meshes had higher rates of erosion pointing to material specific properties. [4] [5] [6] Microporous material with low tissue adherence, such as expanded polytetrafluoroethylene (ePTFE) also showed a high exposure rate. [7] Comparatively, meshes made out of the same material, polypropylene, but with a different pore size showed an advantage of the larger pore designs. [2] In addition to the lower tissue adherence, meshes with smaller pores do not allow tissue ingrowth and likely interfere with the vascularisation and innervation of the overlying mucosa. As with all flap surgeries, insufficient neurovascular supply can lead to dystrophic (atrophic) changes and necrosis of a thin flap dependent on a limited lateral supply. For example, animal models showed that the rate of erosion was dependent on mesh size. Larger mesh implants had a higher risk of exposure. [8] [9]

Overall, the published literature and cumulative clinical experience demonstrated that the risks of mucosal erosion are dependent on the design. [3] [10] [11] [12] [13] The objects become exposed because they do not become an integral and physiological tissue component, but rather remain a foreign body that can damage the tissues, interrupt healing, and is targeted for destruction, encapsulation and expelling. [14] [15] [16] [17] [18] [19] The degree of these negative effects is dependent on an overall device design and it may take many months, years or even decades before the negative effects become clinically apparent.

## **II. General Issues of Infection and Specifics of Mersilene Mesh**

As for any foreign object, infection can be either introduced with the mesh during implantation, or the device can become seeded later. A secondary contamination can occur either through the wound of mesh erosion (skin or mucosa), or hematogeneously, through blood stream from a distant site such as a distant wound. There can also be a combination of sources that would have a compounding effect. In either scenario, surface and spaces within the mesh structure provide opportunities for bacterial adhesion and shelter. Therefore, characteristics of a material and the overall design of a device are the most important modifiable factors effecting the risk of infection.

Presence of bacteria on the implant can be dormant for a long time. It has been shown that adhered bacteria can be seen in up to a third of explanted meshes. [20] However, in many cases presence of infection is subclinical. Bacteria have been detected on meshes explanted for reasons other than a clinically apparent infection. Several studies indicated that there is a delay of several months or years before the infection can manifest clinically. [21] [22] [23] [24] [25] [26] [27] Therefore, length of either experimental or clinical studies is important to accurately assess the risks of infection for a particular mesh design.

Historically, it has been noted during the early search for better mesh materials that constructs with smaller spaces in the mesh structure are more prone to retain infection. Smaller spaces also limit tissue ingrowth through the mesh. Multifilament sutures, in comparison to monofilament ones, were known to be prone to infection for several decades. [28] The earlier reports of infections associated with multifilament mesh (Mersilene) date back to at least 1970s. [29] Also in 1970s an experimental study showed that immobile bacteria can propagate inside

multifilament materials. The spreading was correlated to the capillary properties of the threads. [30] These experimental results comparing suture materials were further supported by other studies in the 1980s. [31] [32] [33] Later studies indicated that microporous, multifilament and composite meshes contain spaces with limited access for the immune cells, and therefore introduced higher risks for bacterial retention and spread. [34] [35] [36] [37] Multifilament meshes also have a larger surface area compared to monofilament designs. [26] Accordingly, in experimental settings, there was a trend for higher volumes of bacteria adherent to multifilament mesh. [26] [38]

By the 1990s the volume of meshes used for hernia repair provided sufficient data to draw long term conclusions. For example, a study concluded: “multifilament polyester mesh had a significantly higher mean number of complications per patient (4.7 vs 1.4-2.3;  $P < .002$ ), a higher incidence of fistula formation (16% vs 0%-2%;  $P < .001$ ), a greater number of infections (16% vs 0%-6%;  $P < .05$ ), and more recurrent hernias (34% vs 10%-14%;  $P < .05$ ) than the other materials used.” [27]

One of the key parameters in mesh design is to allow a free traffic of the immune cells - neutrophils. These cells are recruited by the body to fight bacterial infections. [1] This knowledge was transferred to mesh designs and classifications. [39] [40] [41] [42] [34] Larger spaces within mesh (larger porosity) allow tissue ingrowth and free traffic of immune cells, while smaller spaces restrict both physiological functions. Mesh constructs with larger spaces throughout the entire mesh were classified as type I; those with only small spaces were grouped as class II; and more complex constructs with a range of spaces (mixed micro-and microporous) were designated as class III:

*Type I:* Totally macroporous prostheses, such as Atrium, Marlex, Prolene and Trelex. These prostheses contain pores larger than 75 microns, which is the required pore size for admission of macrophages, fibroblasts (fibroplasia), blood vessels (angiogenesis) and collagen fibers into the pores [Bobyne et al. 1982, White 1988, White et al. 1981].

*Type II:* Totally microporous prostheses, such as expanded PTFE (Gore-

Tex), Surgical Membrane, and Dual-mesh. These prostheses contain pores that are less than 10 microns in at least one of their three dimensions.

*Type III:* Macroporous prosthesis with multifilamentous or microporous components, such as PTFE mesh (Teflon), braided Dacron mesh (Mersilene), braided polypropylene mesh (Surgipro) and perforated PTFE patch (MycroMesh).

*Type IV:* Biomaterials with submicronic pore size, such as silastic, Cellgard (polypropylene sheeting), Preclude Pericardial membrane and Preclude Dura-substitute. These are not suitable prostheses for hernia repair; however, in combination with Type I biomaterials, they can provide adhesion-free composites for intraperitoneal implantation [Amid et al

[34]

Multifilament meshes are a typical class III design since they have larger pores in the knit pattern, but are knitted using multifilament thread that contains smaller spaces between the filaments in the thread. The smaller spaces are a critical component for the risk of infection:

#### Infection

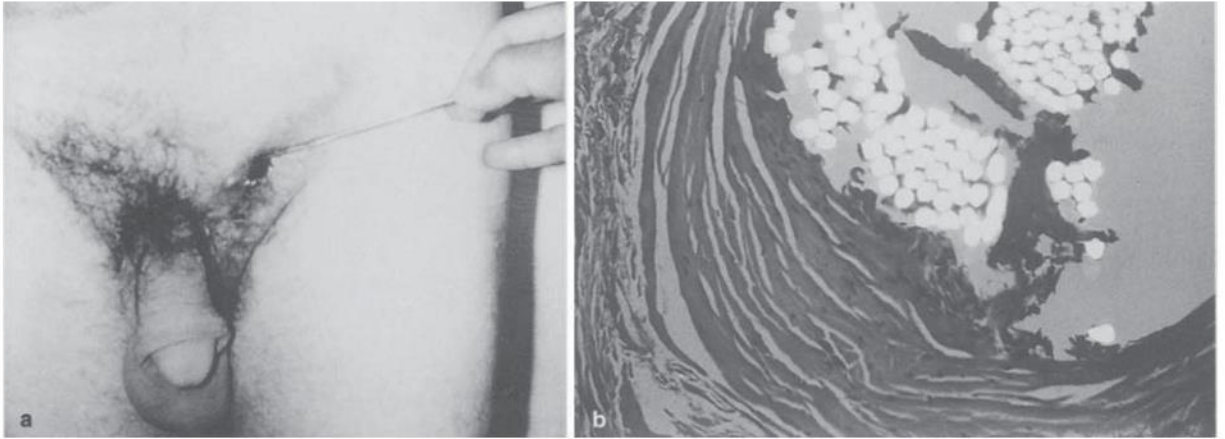
Surgical infection promoted by implantation of biomaterials, such as sutures and prostheses, is caused by infiltration and proliferation of bacteria into and within the pores and interstices of these synthetic materials. When interstices or pores are less than 10 microns, in each of their three dimensions, bacteria ave-

raging 1 micron cannot be eliminated by macrophages and neutrophilic granulocytes, which are too large to enter a 10 microns three-dimensional pore [Alexander et al. 1967, Elek and Conen

1957, Neel 1983]. Braided sutures [Elek and Conen 1957] and prosthetic material [Neel 1983] with interstices and pores less than 10 microns provide a suitable housing for bacteria and deve-

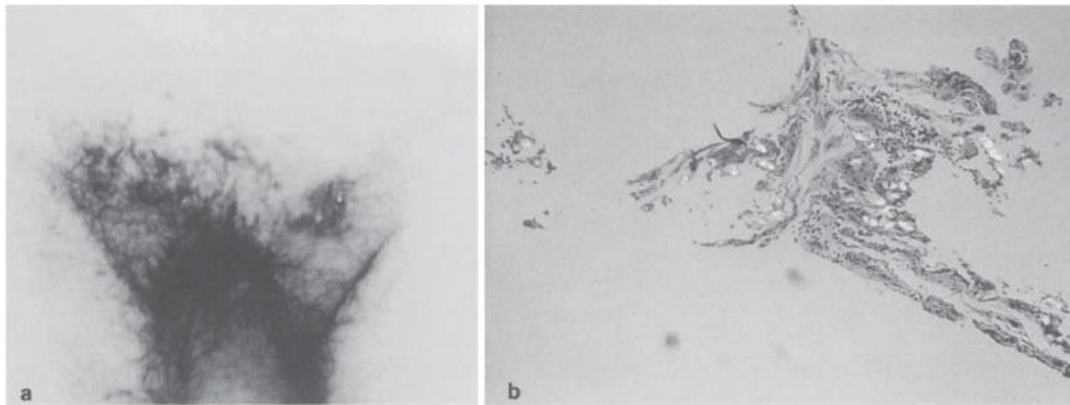
lopment of infection by admitting bacteria but excluding macrophages. By admitting both macrophages and bacteria, biomaterials with pores larger than 10 microns create a major challenge for the proliferation of bacteria, and thus do not contribute to the development of surgical infection [Larson and Harrower 1978, Law and Ellis 1991, Martin et al. 1982, Usher et al. 1959].

Type II and III prostheses are similar to braided suture materials, and by harboring bacteria can promote their growth, likewise resulting in biomaterial-related infection [Alexander et al. 1967, Elek and Conen 1957]. Figure 1 is an example of an infected and partially extruded Type II prosthesis; Figure 2a and b, of an infected Type III.



**Fig. 2a, b**

**a** Chronic infection and sinus tract formation after hernia repair with Surgipro. **b** Multifilamentous fibers of Surgipro surrounded by inflammatory cells (polarized lighting)



**Fig. 3a, b**

**a** Chronic infection and sinus tract formation after hernia repair with Marlex mesh, sutured in place with braided suture material. **b** Braided suture material surrounded by inflammatory cells (polarized lighting)

[34]



Mersilene mesh is a class III complex mesh that combines both macro- and microporous structures:

TABLE 1 The classification of synthetic biomaterials; adapted from Karlovsky et al. [4]

Synthetic material (manufacturer)	Filamentous structure	Mesh type	Pore size
Polypropylene, Marlex (CR Bard, Covington GA)	Monofilament	I	Macro
Polypropylene, Prolene (Ethicon, Somerville NJ)	Monofilament	I	Macro
Polypropylene, Atrium (Atrium Medical, Hudson NH)	Monofilament	I	Macro
Polypropylene, TVT (Johnson and Johnson, New Brunswick NJ)	Monofilament	I	Macro
Polypropylene, SPARC (American Medical Systems)	Monofilament	I	Macro
Polypropylene, Lynx (Boston Scientific, Natick, MA)	Monofilament	I	Macro
Polypropylene, T-Sling (Caldera Medical, Augura Hills, CA)	Monofilament	I	Macro
PTFE (Teflon, CR Bard)	Multifilament	III	Micro
Expanded PTFE, Gore-Tex (W.L. Gore, Flagstaff AZ)	Multifilament	II	Micro
Polyethylene tetraphthalate, Mersilene (Ethicon)	Multifilament	III	Macro/micro
Polyester-silicone coated, Internesh (American Medical Systems)	Multifilament	IV	Submicro
Polyglycolic acid, Dexon (Davis and Geck, Danbury CT)	Multifilament	Absorbable	Macro
Polyglactin 910, Vicryl (Ethicon)	Multifilament	Absorbable	Macro

[43]

The earliest attempts to use multifilament mesh (Mersilene) for pelvic surgeries were in the 1960s. [44] Among other results the publications reported suprapubic abscess and chronic sinus formation. Later, erosions, infection and formation of chronic sinus were reported in 1990s for Mersilene mesh used for pelvic prolapse surgeries. [45] [46] A publication stated: “This procedure is not recommended as a primary procedure for the repair of the anterior vaginal segment. It is reserved for patients who have had two or more reparative failures.” [46] More data were accumulated by 2000. A larger study followed 273 patients who underwent colpopexy using Mersilene mesh. They reported an overall erosion rate of 5.5%. [47] The study did not aim to detect the life-long risk of mesh erosion, but rather focused on comparison of different surgical approaches. Since for the most groups the median follow up time was shorter than the median time it took for erosions to appear, the 5.5% rate reflected only the earlier erosions (median follow up

time vs. time before erosion was shorter in three out of four groups: 6.5 vs. 15.6; 4.9 vs. 12.4; 6.1 vs. 9.0; 6.6 vs. 4.1 months):

among the various vault suspensions. The overall mean follow-up time was  $12.3 \pm 16.7$  months, and the median length of follow-up was 5.8 months (range, 1-87 months). The median length of follow-up was 6.5 months (range, 1-87 months) for abdominal sacral colpopexy, 4.9 months (range, 1-45 months) for abdominal sacral colpoperineopexy, 6.1 months (range, 1-28 months) for vaginally passed sutures, and 6.6 months (range, 2-11 months) for vaginally placed mesh. The median number of months to appearance of mesh erosion was 15.6 (range, 2-33 months) in the abdominal-only sacral colpopexy group, 12.4 months (range, 3-40 months) in the abdominal-only sacral colpoperineopexy group, 9.0 months (range, 5-15 months) in the suture-only group, and 4.1 months (range, 2-7 months) in the vaginal mesh group.

[47]

Considering that, statistically medians closely represent 50<sup>th</sup> percentile, the life-long rates would be expected more than to double with a sufficiently long follow up time. The authors acknowledged that most erosions occur within two years after mesh implantation and some occur many years later:

The time to vaginal mesh erosion seems to be quite variable with most erosions occurring within the first 2 years after surgery but some occurring many years later.

The study did not detect patient specific factors affecting the rates of mesh erosion:

The variables *age, weight, parity, estrogen status, concomitant hysterectomy, and posterior repair* were examined; however, none was found to be independently associated with mesh erosion. Because various types of permanent suture material were used to secure the mesh to the vagina, we divided the colpopexies into 2 groups—those that used monofilament suture and those that used braided suture. Mesh erosion was independent of type of suture used.

The authors considered mesh infection as one of the causes of erosions:

Mesh erosions may be the only clinical manifestation of a bacterial contamination. If this is true, it supports our

They also recognized that infection can be either primary or secondary event:

could explain this finding. By definition, the eroded mesh is directly exposed to the vagina; therefore it is difficult to know whether a positive culture of the mesh antedated the erosion or whether it was the result of post-erosion exposure of the mesh to the vaginal flora.

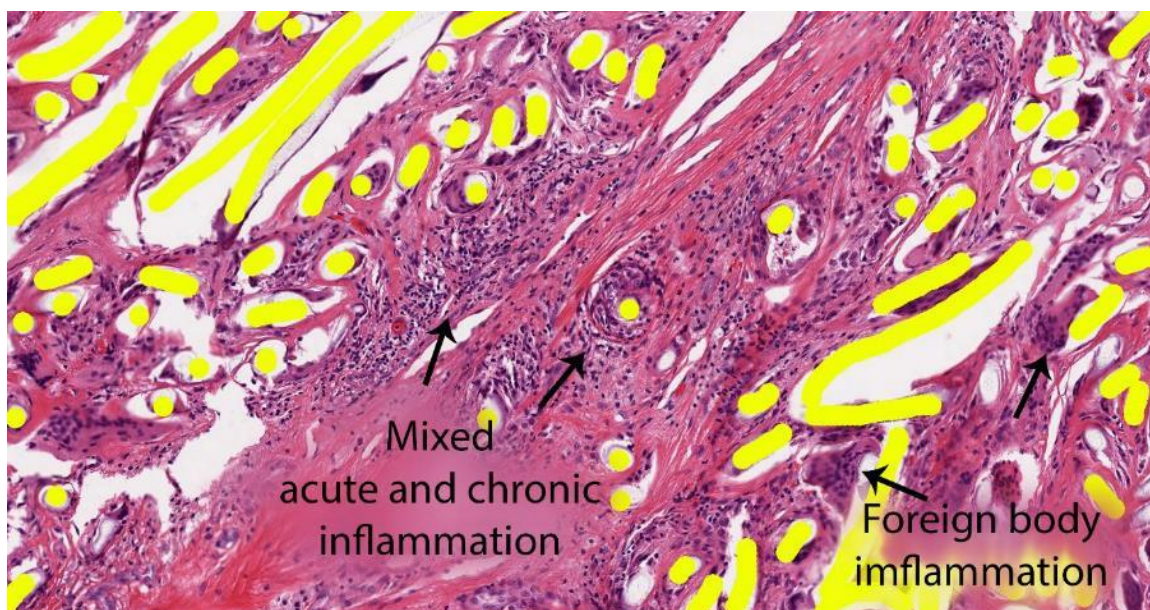
The final conclusion in the publication was that new materials are needed to lower the erosion rates:

uture length, and then to the sacrum is an important principle. In the future the development of other types of synthetic mesh, the use of biologic and potentially less reactive materials, or the combined use of these materials may provide reliable and strong support with fewer erosions.

[47]

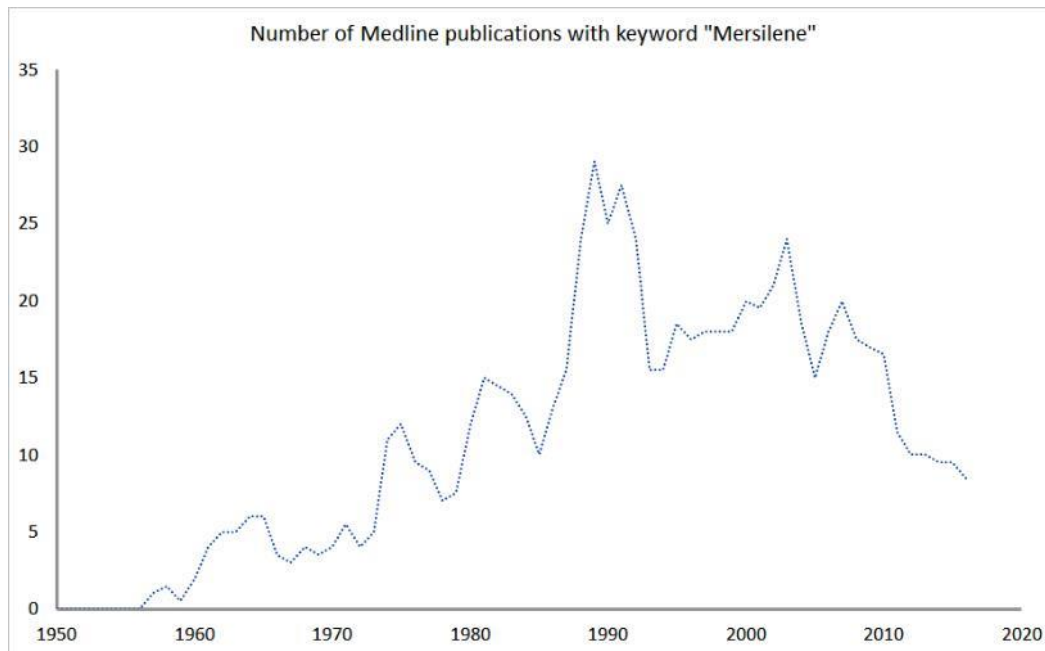
These conclusions were in line with the earlier studies and mesh classification based on the hernia surgical experience. The multifilament mesh design was determined to have higher risks of infection, and the risk was design-specific.

For midurethral slings, multifilament polypropylene, not polyester meshes were attempted as a material for prefabricated devices. These devices have been used only for several years but the experience was sufficient to show that rates of infection and erosion were significantly higher than for the monofilaments designs. [48] [49] [50] [51] [52] [53] [2] [54] [55] [56] [57] [58] A number of reports described deep infection and subsequent formation of abscesses and more extensive tissue necrosis. [59] [60] [61] [62] [63] [64] [65] These devices left a strong trail of publications describing erosions and infections.



**Infected multifilament polypropylene mesh. [36]**

The above described experiences and knowledge affected use and introduction of new multifilament mesh designs. For example, in published literature, an annual number of publications with the keyword “Mersilene” listed on PubMed declined significantly since the 1990s.



The graph above was plotted using data generated by:

<http://dan.corlan.net/medline-trend.html>

I reserve the right to supplement this report if new information becomes available.

Vladimir Iakovlev, MD, FRCPC, FCAP

DATE: June 23, 2018

## Materials referenced in the report

- [1] Kumar V, Abbas A, Fausto N, Aster J, Robbins and Cotran Pathological Basis of Disease, 7th and 8th Editions, Elsevier, Imprint: W.B. Saunders, 2004 and 2010.
- [2] Yamada BS, Govier FE, Stefanovic KB, Kobashi KC, "High rate of vaginal erosions associated with the mentor ObTape," *J Urol*, vol. 176, no. 2, pp. 651-4, 2006.
- [3] J. G. Blaivas, R. S. Purohit, M. S. Benedon, G. Mekel, M. Stern, M. Billah, K. Olugbade, R. Bendavid, V. Iakovlev., "Safety considerations for synthetic sling surgery.," *Nature Reviews Urology*, vol. 12, no. 9, pp. 481-509, 2015.
- [4] Govier FE, Kobashi KC, Kuznetsov DD, Comiter C, Jones P, Dakil SE, James R Jr, "Complications of transvaginal silicone-coated polyester synthetic mesh sling," *Urology*, vol. 66, no. 4, pp. 741-5, 2005.
- [5] Chin YK, Stanton SL, "A follow up of silastic sling for genuine stress incontinence," *Br J Obstet Gynaecol*, vol. 102, no. 2, pp. 143-7, 1995.
- [6] Duckett JR, Constantine G, "Complications of silicone sling insertion for stress urinary incontinence," *J Urol*, vol. 163, no. 6, pp. 1835-7, 2000.
- [7] Bent AE, Ostergard DR, Zwick-Zaffuto M, "Tissue reaction to expanded polytetrafluoroethylene suburethral sling for urinary incontinence: clinical and histologic study," *Am J Obstet Gynecol*, vol. 169, no. 5, pp. 1198-204, 1993.
- [8] Manodoro S, Endo M, Uvin P, Albersen M, Vlácil J, Engels A, Schmidt B, De Ridder D, Feola A, Deprest J, "Graft-related complications and biaxial tensiometry following experimental vaginal implantation of flat mesh of variable dimensions," *BJOG*, vol. 120, no. 2, pp. 244-50, 2013.
- [9] Pierce LM, Rao A, Baumann SS, Glassberg JE, Kuehl TJ, Muir TW, "Long-term histologic response to synthetic and biologic graft materials implanted in the vagina and abdomen of a rabbit model," *Am J Obstet Gynecol*, vol. 200, no. 5, pp. 546.e1-8, 2009.
- [10] Cornu JN, Peyrat L, Haab F., "Update in management of vaginal mesh erosion.," *Curr Urol Rep*, vol. 14, no. 5, pp. 471-5, 2013.
- [11] Schimpf MO, Abed H, Sanses T, White AB, Lowenstein L, Ward RM, Sung VW, Balk EM, Murphy M; Society of Gynecologic Surgeons Systematic Review Group., "Graft and



- Mesh Use in Transvaginal Prolapse Repair: A Systematic Review.," *Obstet Gynecol*, vol. 128, no. 1, pp. 81-91, 2016.
- [12] Milose JC, Sharp KM2, He C1, Stoffel J1, Clemens JQ1, Cameron AP, "Success of autologous pubovaginal sling after failed synthetic mid urethral sling," *J Urol*, vol. 193, no. 3, pp. 916-20, 2015.
- [13] Welk BK, Herschorn S., "The autologous fascia pubovaginal sling for complicated female stress incontinence.," *Can Urol Assoc J*, vol. 6, no. 1, pp. 36-40., 2012.
- [14] MONRO RS, "Extrusion of an inhaled foreign body through the chest wall," *Postgrad Med J*, vol. 36, pp. 50-2, 1960.
- [15] Wesley RE, Wahl JW, Loden JP, Henderson RR, "Management of wooden foreign bodies in the orbit," *South Med J*, vol. 75, no. 8, pp. 924-6, 1982.
- [16] Fukamachi A, Wada H, Toyoda O, Wakao T, Kawafuchi J, "Migration or extrusion of shunt catheters," *Acta Neurochir (Wien)*, vol. 64, no. 1-2, pp. 159-66, 1982.
- [17] Morecraft RJ, Blair WF, Maynard JA, "Suture extrusion in small arteries and veins," *Scand J Plast Reconstr Surg Hand Surg*, vol. 22, no. 2, pp. 121-6, 1988.
- [18] POWELL MM, "Catheter migration from uterus to lung, perforating the diaphragm; a case report," *Dis Chest*, vol. 30, no. 5, pp. 583-4, 1956.
- [19] TULLOH CG, "Migration of intra-ocular foreign bodies," *Br J Ophthalmol*, vol. 40, no. 3, pp. 173-7, 1956.
- [20] Klosterhalfen B, Klinge U, Hermanns B, Schumpelick V., "Pathology of traditional surgical nets for hernia repair after longterm implantation in humans," *Chirurg*, vol. 71, pp. 43-51, 2000.
- [21] Slim K, Pezet D, Le Roux S, Chipponi J., "Mesh infection after laparoscopic herniorrhaphy," *Eur J Surg*, vol. 162, pp. 247-248, 1996.
- [22] Foschi D, Corsi F, Cellerino P, Trabucchi A, Trabucchi E., "Late rejection of the mesh after laparoscopic hernia repair.," *Surg Endosc*, vol. 12, pp. 455-457, 1998.
- [23] Coda A, Micca F, Bossotti M., "Reoperations for chronic infections following prosthetic hernia repair.," *Hernia*, vol. 2, pp. 163-167, 1998.

- [24] Hofbauer C, Andersen PV, Juul P, Qvist N., "Late mesh rejection as a complication to transabdominal preperitoneal laparoscopic hernia repair.," *Surg Endosc*, vol. 12, pp. 1164-1165, 1998.
- [25] Tylor S, O'Dwyer P., "Chronic groin sepsis following tensionfree inguinal hernioplasty.," *Br J Surg*, vol. 86, pp. 562-565, 1999.
- [26] Klinge U., Junge K., Spellerberg B., Piroth C., Klosterhalfen B, Schumpelick V. , "Do Multifilament Alloplastic Meshes Increase the Infection Rate? Analysis of the Polymeric Surface , the Bacteria Adherence, and the In Vivo Consequences in a Rat Model.," *J Biomed Mater Res (Appl Biomater)*, vol. 63, pp. 765-771, 2002.
- [27] Leber GE, Garb JL, Alexander AI, Reed WP., "Long-term complications associated with prosthetic repair of incisional hernias.," *Arch Surg*, vol. 133, pp. 378-382, 1998.
- [28] Van Winkle W Jr, Hastings JC, Barker E, Hines D, Nichols W., "Effect of suture materials on healing skin wounds.," *Surg Gynecol Obstet*, vol. 140, no. 1, pp. 7-12, 1975.
- [29] McCollough EG, Weil C., "Augmentation of facial defects using Mersilene mesh implants.," *Otolaryngol Head Neck Surg*, vol. 87, no. 4, pp. 515-21, 1979.
- [30] Blomstedt B, Osterberg B, Bergstrand A., "Suture material and bacterial transport. An experimental study," *Acta Chir Scand*, vol. 143, no. 2, pp. 71-3, 1977.
- [31] Sharp WV, Belden TA, King PH, Teague PC., "Suture resistance to infection.," *Surgery*, vol. 91, no. 1, pp. 61-3, 1982.
- [32] Osterberg B., "Enclosure of bacteria within capillary multifilament sutures as protection against leukocytes.," *Acta Chir Scand.*, vol. 149, no. 7, pp. 663-8, 1983.
- [33] Bucknall TE., "Factors influencing wound complications: a clinical and experimental study.," *Ann R Coll Surg Engl.*, vol. 65, no. 2, pp. 71-7, 1983.
- [34] Amid P, "Classification of biomaterials and their related complications in abdominal wall hernia surgery," *Hernia*, vol. 1, pp. 5-8, 1997.
- [35] Rastegarpour A, Cheung M, Vardhan M, Ibrahim MM, Butler CE, Levinson H., "Surgical mesh for ventral incisional hernia repairs: Understanding mesh design.," *Plast Surg (Oakv)*, vol. 24, no. 1, pp. 41-50, 2016.



- [36] Iakovlev V, Blaivas J., "The Reason Why Some Sling Designs Can Be Prone to Infection," *The World Journal of Urology*, vol. 34, no. 1S, pp. 230, UP337, 2016.
- [37] Sanders D, Lambie J, Bond P, Moate R, Steer JA., "An in vitro study assessing the effect of mesh morphology and suture fixation on bacterial adherence.," *Hernia*, vol. 17, no. 6, pp. 779-89, 2013.
- [38] Shuhaiber H, Chugh T, Burns G., "In vitro adherence of bacteria to sutures in cardiac surgery.," *J Cardiovasc Surg*, vol. 30, pp. 749-753, 1989.
- [39] Alexander JW, Kaplan JZ, Altemeier WA., "Role of suture materials in the development of wound infection," *Ann Surg*, vol. 165, no. 2, pp. 192-9, 1967.
- [40] Sharp WV, Belden TA, King PH, Teague PC., "Suture resistance to infection," *Surgery*, vol. 91, no. 1, pp. 61-3, 1982.
- [41] Osterberg B., "Influence of capillary multifilament sutures on the antibacterial action of inflammatory cells in infected wounds.," *Acta Chir Scand*, vol. 149, no. 8, pp. 751-7, 1983.
- [42] Osterberg B., "Enclosure of bacteria within capillary multifilament sutures as protection against leukocytes.," *Acta Chir Scand*, vol. 149, no. 7, pp. 663-8, 1983.
- [43] Winters JC, Fitzgerald MP, Barber MD., "The use of synthetic mesh in female pelvic reconstructive surgery," *BJU Int*, vol. 98, no. Suppl 1 , pp. 70-6; discussion 77, 2006.
- [44] WILLIAMS TJ, TELINDE RW., "The sling operation for urinary incontinence using mersilene ribbon.," *Obstet Gynecol*, vol. 19, pp. 241-5, 1962.
- [45] Creighton SM, Stanton SL., "The surgical management of vaginal vault prolapse.," *Br J Obstet Gynaecol*, vol. 98, no. 11, pp. 1150-4, 1991.
- [46] Julian TM, "The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall.," *Am J Obstet Gynecol*, vol. 175, no. 6, pp. 1472-5, 1996.
- [47] Visco AG, Weidner AC, Barber MD, Myers ER, Cundiff GW, Bump RC, Addison WA, "Vaginal mesh erosion after abdominal sacral colpopexy," *Am J Obstet Gynecol*, vol. 184, no. 3, pp. 297-302, 2001.
- [48] Bafghi A, Benizri EI, Trastour C, Benizri EJ, Michiels JF, Bongain A., "Multifilament polypropylene mesh for urinary incontinence: 10 cases of infections requiring removal of the sling.," *BJOG*, vol. 112, no. 3, pp. 376-8, 2005.

- [49] Kaelin-Gambirasio I, Jacob S, Boulvain M, Dubuisson JB, Dällenbach P., "Complications associated with transobturator sling procedures: analysis of 233 consecutive cases with a 27 months follow-up.," *BMC Womens Health*, vol. 9, p. 28, 2009.
- [50] Tahseen S, Reid PC, Charan P., "Short-term complications of the trans-obturator foramen procedure for urinary stress incontinence.," *J Obstet Gynaecol*, vol. 27, no. 5, pp. 500-2, 2007.
- [51] Giberti C, Gallo F, Cortese P, Schenone M., "Transobturator tape for treatment of female stress urinary incontinence: objective and subjective results after a mean follow-up of two years.," *Urology*, vol. 69, no. 4, pp. 703-7, 2007.
- [52] Onyeka BA, Ogah J., "Vaginal tape erosion following transobturator tape (TOT) operation for stress urinary incontinence.," *J Obstet Gynaecol*, vol. 26, no. 8, pp. 802-3, 2006.
- [53] Abdel-Fattah M, Sivanesan K, Ramsay I, Pringle S, Bjornsson S., "How common are tape erosions? A comparison of two versions of the transobturator tension-free vaginal tape procedure.," *BJU Int.* , vol. 98, no. 3, pp. 594-8, 2006.
- [54] Dobson A, Robert M, Swaby C, Murphy M, Birch C, Mainprize T, Ross S., "Trans-obturator surgery for stress urinary incontinence: 1-year follow-up of a cohort of 52 women," *Int Urogynecol J Pelvic Floor Dysfunct*, vol. 18, no. 1, pp. 27-32, 2007.
- [55] Deval B, Ferchaux J, Berry R, Gambino S, Ciofu C, Rafii A, Haab F., "Objective and subjective cure rates after trans-obturator tape (OBTAPPE) treatment of female urinary incontinence.," *Eur Urol*, vol. 49, no. 2, pp. 373-7, 2006.
- [56] Siegel AL., "Vaginal mesh extrusion associated with use of Mentor transobturator sling.," *Urology*, vol. 66, no. 5, pp. 995-9, 2005.
- [57] Spinosa JP, Dubuis PY, "Suburethral sling inserted by the transobturator route in the treatment of female stress urinary incontinence: preliminary results in 117 cases.," *Eur J Obstet Gynecol Reprod Biol*, vol. 123, no. 2, pp. 212-7, 2005.
- [58] Juma S, Brito CG, "Transobturator tape (TOT): Two years follow-up," *Neurourol Urodyn*, vol. 26, no. 1, pp. 37-41, 2007.
- [59] Lowery WJ, Dooley Y, Kost E, "Small-pore polypropylene slings: still out there," *Int Urogynecol J*, vol. 21, no. 1, pp. 125-7 , 2010.

- [60] Geoffrion R, Murphy M, Mainprize T, Ross S, "Closing the chapter on obtape: a case report of delayed thigh abscess and a literature review," *J Obstet Gynaecol Can*, vol. 30, no. 2, pp. 143-7, 2008.
- [61] Yeung P Jr, Sokol A, Walton B, Iglesia C, "Thigh abscess mistaken for sarcoma following transobturator tape: a case report and literature review.," *J Minim Invasive Gynecol*, vol. 14, no. 5, pp. 657-9, 2007.
- [62] DeSouza R, Shapiro A, Westney OL, "Adductor brevis myositis following transobturator tape procedure: a case report and review of the literature," *Int Urogynecol J Pelvic Floor Dysfunct*, vol. 18, no. 7, pp. 817-20, 2007.
- [63] Ismail SI., "Mesh infection without erosion after ObTape sling insertion: a diagnostic challenge," *Int Urogynecol J Pelvic Floor Dysfunct*, vol. 18, no. 9, pp. 1115-8., 2007.
- [64] Marques AL, Aparício C, Negrão L., "Perineal cellulitis as a late complication of trans-obturator sub-urethral tape, Obtape," *Int Urogynecol J Pelvic Floor Dysfunct*, vol. 18, no. 7, pp. 821-2, 2007.
- [65] Babalola EO, Famuyide AO, McGuire LJ, Gebhart JB, Klingele CJ., "Vaginal erosion, sinus formation, and ischiorectal abscess following transobturator tape: ObTape implantation," *Int Urogynecol J Pelvic Floor Dysfunct*, vol. 17, no. 4, pp. 418-21, 2006.